UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,437	03/26/2004	Gene A. Bornzin	A04P1029	9799

36802 7590 06/12/2007

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,437	BORNZIN ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 19-35* is/are rejected.

7)☒ Claim(s) *17 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/04, 09/05, 05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on March 26, 2004, September 21, 2005 and May 26, 2006 have been acknowledged and are being considered by the Examiner.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application-by-application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath/declarations do not have the correct statement with respect to the duty to disclose. This applies to all applications, not just reissue applications.

A CORRECT STATEMENT should read, "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

INCORRECT STATEMENTS:

"I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)."

"I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)."

"I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Specification

3. The abstract of the disclosure is objected to because it contains phrases such as "techniques are provided", which may be implied. Correction is required. See MPEP § 608.01(b).

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

5. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 previously limits the method to include averaging the values representative of ventricular end-diastolic volume (EDV).

6. Claims 14 and 19 are objected to because of the following informalities: there exists an inadvertatnt typographical error in the seventh line of the claims. The Examiner suggests changing "of the impedance between" to read "of an impedance between" in order to avoid an antecedent basis problem. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3, 14-18 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 3 recites the limitation "for each cycle" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

10. Claims 14 and 19 recite the limitation "the ventricles" in the 2nd - 3rd lines of the claims. There is insufficient antecedent basis for these limitations in the claims. Claims 15-18 depend from Claim 14 and the deficiencies of Claim 14 are imputed to all dependent claims. Claims 20-22 depend from Claim 19 and the deficiencies of Claim 19 are imputed to all dependent claims.

11. Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: detecting values representative of passive filling. Specifically, the Examiner suggests amending Claim 1 to include this limitation or amending the entire preamble of Claim 19 to read something similar to, "The method of Claim 1 further comprising detecting values representative of passive filling using at least two electrodes for implant within both ventricles of the patient and wherein detecting values representative of passive filling comprises:" in order to add positive limitation that the method includes detecting values representative of passive filling. Claims 20-22 depend from Claim 19 and the deficiencies of Claim 19 are imputed to all dependent claims.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 1-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, Applicant's claims are directed to a judicial exception of 35 U.S.C. 101. The method claims of the present application relate to abstract ideas, rather than practical applications of those ideas. Specifically, the claims do not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result. See MPEP § 706.03(a).

To overcome the rejection, in specific reference to Claim 1, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "detecting" by "performing an action" or "completing a method step" using a device/system of some sort. For example, incorporating the limitations of Claim 23 into Claim 1 would overcome the 35 U.S.C. 101 rejections against Claims 1-5 and 8-22 because the modification would require the method to use detection of heart failure to produce a tangible result (i.e. administration of therapy).

To overcome the rejection, in specific reference to Claim 6, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "evaluating" by "performing an action" or "completing a method step" using a device/system of some sort. For example, incorporating the limitations of Claim 24 and any intervening claims into Claim 6 would overcome the 35 U.S.C. 101 rejections against Claims 6 and 7

because the modification would require the method to use evaluation of heart failure to produce a tangible result (i.e. adjustment of therapy).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-2, 5-6, 8-9, 14, 23-24, 27-29 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg (U.S. 6,314,322). As to 1, 5-6, 8-9, 23-24, 27-29 and 32-33, Rosenberg discloses a method for evaluating congestive heart failure within a patient using an implantable medical device 20 (see Rosenberg Figs. 1-2 and 4, Abstract, columns 1-3, column 4, lines 1-50 and column 8, lines 31-65). Specifically, the method of Rosenberg may utilizes an acoustic sensor 40 as an end-diastolic volume (EDV) sensor, read as a ventricular end-diastolic detection unit 22 to detect reflected sound waves, read as values representative of EDV of the patient. Rosenberg specifies that a piezoelectric crystal 42 emits sound waves into the left ventricle 16 when the ventricle 16 is filled with blood 11 and further that "sound waves reflected from the different tissue interfaces in the heart propagate back to the piezoelectric crystal 42, where the time differences between emitted and detected pulses are proportional to ventricular dimensions" (see Rosenberg column 5, lines 10-67 and column 6, lines 1-34). Rosenberg further discloses that the values are used in an algorithm by a diastolic monitor, read as a ventricular EDV-based heart failure evaluation unit 30 to calculate ventricular wall stress, read as values

representative of EDV in order to detect heart failure and evaluate if the heart failure has worsened or improved on a beat-to-beat basis. Rosenberg expressly discloses that for each cardiac cycle, a worsening condition is detected by the ventricular EDV-based heart failure evaluation unit 30 by comparing ventricular wall stress, read as a value of ventricular EDV against a threshold or reference value (i.e. the stress value for the previous beat or the reference stress value determined at the start of the algorithim) and if the value is greater than the threshold/reference (i.e. the stress has worsened and the heart failure has gotten more severe over time), the heart-failure therapy controller 32 shortens the pacing time in an effort to maintain the ventricular stress at a constant level. It is inherent that the system of Rosenberg stores the threshold/reference value since it is used for comparison each time a new value is measured in a subsequent cycle (see Rosenberg Fig. 4 and column 8, lines 55-65).

16. As to Claim 2, Rosenberg expressly discloses that ventricular EDV-based heart failure evaluation unit 30 requests and receives the values immediately prior to the fireing of the pacing signal, read as during a pre-ejection interval (see Rosenberg column 8, lines 50-65).

17. As to Claim 14, ventricular EDV-based heart failure evaluation unit 30 identifies a baseline point within a cardiac cycle at the end of diastole and uses the ventricular stress value at that point as previously discussed (see Rosenberg column 8, lines 21-65). Rosenberg further specifies that the method may also include detecting a signal representative of an impedance between two ventricular electrodes at the baseline point in time such that the sensed impedance, read as a baseline ventricular EDV value based on the impedance signal may be used to supplement the other measured and calculated values used by the algorithm of the device 20 (see Rosenberg column 8, lines 66-67 and column 9, lines 1-19).

18. Claims 1, 3, 5-10, 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bardy (U.S. 6,336,903). As to Claim 1, Bardy expressly discloses a method for evaluating heart failure within a patient 11 using an implantable medical device 12 (see Bardy Fig. 1, Abstract, column 3, lines 15-67, column 4, lines 1-45, column 5, lines 39-67, column 6, lines 1-52 and column 7, lines 18-66). The method of Bardy comprises detecting pulmonary artery diastolic pressure (PADP) values, which reflect left ventricular filling pressure and a measure of left ventricular dysfunction. Bardy expressly discloses that PADP values are measured alternatively to left ventricular end diastolic pressure (LVEDP), thus the Examiner interprets the PADP values to be synonymous to values representative of ventricular end-diastolic volume (EDV) (see Bardy Fig. 11A, Block 176 and column 15, lines 20-33). The method of Bardy further comprises detecting transthoracic impedance, which is also considered by the Examiner to be synonymous with values representative of EDV (see Bardy Fig. 11B, block column 179,c olumn 15, lines 5-67 and column 16, lines 1-50). The Examiner makes specific reference to Bardy Fig. 12, which depicts the routine for detecting heart failure, if present, within the patient 11 using the values representative of EDV (see Bardy Fig. 12, column 16, lines 51-67 and columns 17-20).

19. As to Claim 3, Bardy discloses that detecting values representative of ventricular EDV may also include taking a plurality of measurements and selecting a maximum value from the plurality of measurements (see Bardy Figs. 9 and 10, column 13, lines 22-67 and column 14, lines 1-16).

20. As to Claim 5, Bardy expressly discloses that detecting heart failure is performed at block 233 of Fig. 12 (see Bardy Fig. 12 and Figs. 13A-13C) by comparing values representative of the ventricular EDV of the patient against a threshold value indicative of heart failure. For

example, if a value of PAD exceeds a threshold of 25 mm Hg, heart failure is detected (see Bardy column 14, lines 16-67, columns 15-17 and column 18, lines 1-44).

21. As to Claims 6-10, Bardy expressly discloses that the method further includes evaluating the severity in heart failure and the progression/regression of heart failure over time. Each of the measurements made by implantable device 12 (including those previously discussed) are measured over an extended period of time. A calculated change in the standard deviation of each measured value over the extended period of time is compared to various threshold values indicative of various degrees of heart failure. The extended period of time may be a month, a week, about one day and/or one hour may be used (see Bardy column 19, lines 45-67 and column 20, lines 1-62).

22. As to Claim 23, Bardy expressly discloses that the method may further include delivering therapy in response to a detection of heart failure (see Bardy column 17, lines 19-33).

23. As to Claim 27, Bardy expressly discloses that the method may include storing diagnostic information indicative of heart failure in a database 17 (see Bardy Fig. 1, column 6, lines 28-67 and columns 7-8).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 10, 26, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg. As to Claim 10, Rosenberg discloses the claimed invention as previously discussed except it is not specified that the device 20 detect changes in heart failure on a beat-to-beat basis for at least one month. It is inherent, or at least obvious to one having ordinary skill in the art, that the device 20 would attempt to maintain the ventricular stress at a constant level using the method as previously discussed for as long as the device is implanted within a patient in order to be most effective for treatment. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make device 20 of Rosenberg detect changes in heart failure on a beat-to-beat basis for at least one month, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

27. As to Claims 26, 30 and 34, Rosenberg discloses the claimed invention as previously discussed but does not however specify that an implantable drug pump be provided such that the method include administration of a drug in response to the detection and/or evaluation(s) based on the detected values. It would have been obvious to one having ordinary skill in the art at the

time the invention was made to modify the method as taught by Rosenberg, with an implantable drug pump be provided such that the method include administration of a drug in response to the detection and/or evaluation(s) based on the detected values since it was known in the art that treatment of dilated cardiomyopathy generally includes drug treatment (see Rosenberg column 2, lines 17-22).

28. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Salo et al. (U.S. 6,278,894) (herein Salo). Rosenberg discloses the claimed invention as previously discussed except that it is not specified how the impedance between the two ventricular electrodes is detected. The Examiner considers rheographic impedance measurements to be conventional and well known in the art and cites Salo as being but one example. Salo teaches that the impedance between two electrodes is obtained by delivering a detection pulse to two source electrodes, such that current is conducted through some region of the patient's tissue and then measuring the voltage differential between two recording electrodes to determine the impedance therebetween, the voltage differential arising from the conduction of the current pulse through the tissue and the fluid between the recording electrodes. Salo further teaches that it is well known for the amplitude of the detection pulse to be below that which is required to evoke capture (depolarization) of the heart (see Salo Abstract, column 2, lines 49-67, column 3, lines 1-6, column 4, lines 21-67 and columns 5-10).

29. Claims 1, 4-6, 8-13, 23-24, 26-30 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chirife (U.S. 5,174,286) in view of Rosenberg and/or Girouard et al. (U.S. 2003/0055461) (herein Girouard). As to Claims 1, 4-6, 8-9, 23-24, 26, 28-30 and 32-34, Chirife expressly discloses a method for evaluating the hemodynamic status of a patient using an

implantable medical device (see Chirife Fig. 6, Abstract, column 5, lines 39-68 and column 6, lines 1-5) comprising detecting a trailing edge voltage (TEV) of an output capacitor 6 during a ventricular pacing pulse on a beat-to-beat basis (see Chirife column 1, lines 5-19 and lines 52-68, column 2, lines 1-68, column 3, lines 1-35 and column 4, lines 32-44). Chirife specifies that the values of TEV detected during the pacing pulses correspond to end-diastolic volume (EDV) values and that a detected beat-to-beat variation in these detected EDV values may be used as a signal indicative of the hemodynamic status of the patient or to drive a rate responsive pacemaker or to control drug delivery from an implantable drug pump (see Chirife column 1, lines 8-29, column 2, lines 10-58, column 4, lines 32-44 and columns 7-8). System of Chirife comprises a ventricular EDV detection unit at stage 11 of the sensor circuitry shown in Chirife Fig. 6. The sensory circuitry may be incorporated into an implantable rhythm control device or a drug delivery device (see Chirife columns 5-8).

Chirife discloses the claimed invention as previously discussed except that it is not specified that the detected values of ventricular EDV be used to evaluate severity of heart failure and/or to monitor the progression of heart failure in the patient. The Examiner takes the position that it is conventional and well known in the medical art that over time, as congestive heart failure progresses in a patient, ventricular end diastolic volume increases. The Examiner cites both Rosenberg and Girouard as being but two cited examples describing this phenomenon. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Chirife, to include comparing the values on a beat-by-beat bases where if an increase of EDV over the course of two or more cardiac cycles is detected, heart failure is detected as worsening over time and/or as more severe than previous detections since it

is well known in the art that as congestive heart failure in a patient worsens, EDV increases. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Chirife, to include comparing the values on a beat-by-beat bases where if a decrease in EDV over the course of two or more cardiac cycles is detected, heart failure is detected as improving over time and/or as less severe than previous detections since it is well known in the art that as congestive heart failure in a patient worsens, EDV increases. These types of beat-to-beat monitoring techniques of the hemodynamic status in a patient are well known in the medical art and given the knowledge of how increased EDV correlates to progressing heart failure (again, the Examiner references both Rosenberg and Girouard) it would have been obvious to modify Chirife to obtain the invention as specified in the claims.

30. As to Claim 10, the previously modified Chirife reference discloses the claimed invention as previously discussed except it is not specified that the beat-to-beat detected changes in EDV be measured over the course of at least one month. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the method of Chirife detect changes in EDV on a beat-to-beat basis for at least one month, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

31. As to Claims 11-13, Chirife expressly discloses that at least one respiration cycle is tracked in order to determine respiratory rate (RR) and further that detecting values representative of EDV (i.e. TEV as previously discussed) occurs at like baseline points (i.e. during a ventricular pacing pulse) within a plurality of cardiac cycles during each respiratory

cycle and even further that processing the values of EDV over the respiration cycle may include generating an average EDV value (see Chirife column 5, lines 20-43).

32. As to Claim 27, it is inherent that, since the method employs derivation of beat-to-beat changes in the values representative of EDV, the method includes storing at least one value for at least one cardiac cycle for subsequent comparison to the a subsequently detected value during a subsequent cardiac cycle.

33. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chirife in view of Rosenberg and/or Girouard as applied to claims 1 and 23 above, and further in view of Kramer et al. (U.S. 2002/0161410) (herein Kramer). The previously modified Chirife reference discloses the claimed invention as previously discussed except that it is not specified that the therapy comprise cardiac resynchronization therapy (CRT). Kramer, however, teaches that it is well known in the art to treat a dilated ventricle via CRT in an effort to reverse ventricular remodeling (see Kramer entire document). It would have been obvious to one having ordinary skill in the art to modify the method of Chirife in view of Rosenberg and/or Girouard to include delivery of CRT therapy as taught by Kramer, since such a modification would effect reverse ventricular remodeling and would greatly benefit patient suffering from dilated ventricles and/or heart failure.

34. Claims 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chirife view of Rosenberg and/or Girouard as applied to claims 28 and 32 above, and further in view of Bakels et al. (U.S. 6,070,100) (herein Bakels).). The previously modified Chirife reference discloses the claimed invention as previously discussed except that it is not specified that the system comprise an implantable heart failure warning device in communication with the heart

failure detection unit to generate a warning in response to a detection that heart failure in the patient is progressing. The Examiner considers this capability of implantable medical devices to be conventional and well known in the art and cites Bakels as being but one example. Bakels teaches that it is well known for an implantable medical device to send a warning to an external programmer such that an indication that heart failure is progressing in the patient can be determined and used to adjust the programming of the device (see Bakels column 10, lines 25-64. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chirife in view of Rosenberg and/or Girouard to include an implantable heart failure warning device within the implantable device that can send a warning to an external programmer as taught by Bakels, since such a modification would allow optimum programming or reprogramming in the event that the hemodynamic status of the patient was worsening (i.e. heart failure was progressing).

Allowable Subject Matter

35. Claim 17-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

36. Claims 19-22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

37. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel
Patent Examiner 06/08/07
Art Unit 3766

Carl H. Layno
Primary Patent Examiner
Art Unit 3766

CARL LAYNO
PRIMARY EXAMINER
ACTING SPE, AU 3766